

Appl. No. : 09/514,999
Filed : February 29, 2000

Claims 2-9 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner asserts that the insertion of "approximately two times or more" raises the issue of new matter and should be deleted because there is only exemplification of a yield of polyamines of up to 3.2. The Examiner further asserts that this is a matter of written description, not a question of what one of skill in the art would or would not have known.

However, the Examiner did not use appropriate standards for this rejection according to M.P.E.P. and case law.

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). M.P.E.P. 2163.02. The "written description" does not mean that the subject matter of the claim must be described literally, but means that persons of ordinary skill in the art would recognize the claimed invention based on the description.

Further, how a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 370 (CCPA 1971). Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970) .M.P.E.P. 2164.08.

In the present application, a feature of the claimed invention is the decomposition step by nuclease digestion or alkali hydrolysis where polyamines are effectively dissociated from the yeast somatic components as a result of decomposition of a high molecular-weight substance bound with polyamines (e.g., page 3, lines 5-9, and page 5, lines 5-23). Example 3 on page 10 shows a yield of polyamines which was 3.2 times as high as the process without the decomposition step. One of ordinary skill in the art in no way would think that Example 3 shows the upper limit of the claimed process. The decomposition step involves chemical reactions, and one of ordinary skill in the art would certainly think that by conducting the reaction longer, the yield would increase, i.e., exceeding 3.2 times. One of ordinary skill in the art would think that the claimed invention is characterized by conducting the decomposition step itself, and the upper limit should not be limited to the particular example, Example 3, and one of ordinary skill in the

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art could practice the claimed invention even in the absence of the upper limit. A declaration accompanying this Amendment shows that the upper limit of the yield could readily exceeds 3.2 times.

Thus, Applicant respectfully traverse this rejection. However, in order to expedite the prosecution of this application, Applicant have amended Claim 9 by specifying the conditions for further clarification. Applicant respectfully requests withdrawal of this rejection.

Claims 2-9 have also rejected under 35 U.S.C. § 112, first paragraph, because there is insufficient enabling disclosure for an increase in yield of 2-3.2 times. As explained above, one of ordinary skill in the art could readily conduct the claimed invention as amended herein without referring to an upper limit of the yield. Applicant respectfully requests withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 2-9 have been rejected under 35 U.S.C. § 112, second paragraph. The Examiner asserts that the requisite time period for more than 3.2 times in yield of polyamines is not disclosed in the specification. However, as explained above, Example 3 shows 3.2 times as a result of the decomposition step for 18 hours. In Claim 9 as amended herein, the decomposition step is conducted for 0.1-24 hours. One of ordinary skill in the art could readily conduct the claimed invention without referring to any upper limit of the yield. In addition, "a yield" in Claim 9 has been amended to --the yield-- for clarification. Applicant respectfully requests withdrawal of this rejection.

New Claim 10

Claim 10 has been added. Claim 10 recites "2-3.2 times". As explained above and as shown in the declaration, the upper limit should not be limited to 3.2 times, and when conducting the decomposition step longer, the yield can increase as one of ordinary skill in the art could understand. It is respectfully submitted that Claim 10 and the dependent claims are allowable.

CONCLUSION


In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 4, 5, and 9 have been amended as follows:

4 (Thrice amended) The method according to Claim 910, wherein the decomposition step is conducted by digesting the yeast somatic components with nuclease added to a solution containing the yeast somatic components, at a pH value of 3-10 and at a temperature of 10-70°C.

5. (Twice amended) The method according to Claim 910, wherein the decomposition step is conducted by hydrolyzing at 20-100°C the yeast somatic components with alkali added to a solution containing the yeast somatic components at a normality of 0.1-5N.

9 (Twice amended) A method of obtaining polyamines, comprising the steps of:

providing yeast somatic components selected from the group consisting of extracts obtained from yeast by physical crushing, extracts obtained from yeast by autolysis, extracts obtained from yeast with hot water, and yeast RNA compositions;

subjecting said yeast somatic components to nuclease digestion or alkali hydrolysis as a decomposition step for ~~a time period effective~~0.1-24 hours to increase ~~at~~the yield of polyamines recovered in a subsequent recovery step by approximately two times or more as compared with ~~at~~the yield of polyamines recovered in the subsequent recovery step without this decomposition step, said nuclease digestion being conducted by treating the yeast somatic components with nuclease at a pH of 3-10 and at a temperature of 10-70°C, said alkali hydrolysis being conducted by treating the yeast somatic components at normality of 0.1-5N and at a temperature of 20-100°C; and

recovering polyamines from said decomposed components.

Claim 10 has been added.